UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 23, 2007

MEMORANDUM

Subject: Efficacy Review for Antimicrobial Copper Alloys-Group I, EPA Reg. No. 82012-R; DP Barcode: D335573

From: Ibrahim Laniyan, Microbiologist
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8/1/07

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To: Marshall Swindell / Karen Leavy
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Applicant: Copper Development Association Inc.
260 Madison Avenue
New York, New York 10016

Formulation from the Label:

Active Ingredient(s)	% by wt.
Copper	96.2 %
Other Ingredients	3.8 %
Total	100.0 %

I. BACKGROUND

The product, Antimicrobial Copper Alloys-Group I (EPA File Symbol 82012-R), is a new product. The product is a group of copper alloys (171 alloys) containing **95.2% – 99.9%** copper [represented by alloys C11000 (99.9%) and C51000 (94.8%)]. The product is intended for use in the manufacture of touch surfaces. The applicant requested to register the product to support claims for non-food contact bacteria reduction, residual bacteria reduction, and continual bacteria reduction, for use in household, public facilities, commercial areas, animal care, hospital or medical environments, and mass transit systems. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated December 1, 2006), EPA Form 8570-35 (Data Matrix), seventeen studies (MRID Nos. 469996-01 through 469996-17), Statements of No Data Confidentiality Claims for all seventeen studies, and the proposed label.

II. USE DIRECTIONS

The product is designed to be used for the manufacture of touch surfaces of items like bedrails, bed-side tables, carts, water fountains, faucets, door handles, showerheads, toilet hardware, light switches, chair armrests and frames, floor tiles, knobs, physical therapy equipment, elevators, soap dispensers, and lockers.

The proposed label mentions that routine cleaning and sanitization of surfaces is required. "Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required." The surface must remain exposed and uncoated.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sanitizer Test (for inanimate, non-food contact surfaces)
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

Residual Self-Sanitizing Products: The effectiveness of sanitizers that bear claims of residual activity must be supported by data that show that the product continues to reduce the number of challenge microorganisms over an identified period of time. Products with residual self-sanitizing activity keyed to the presence of moisture on surfaces should be tested in a controlled or

simulated in-use study. The study should be designed in consultation with the Agency. Products with residual self-sanitizing activity intended for use on dry surfaces should be tested in accordance with Protocol #01-1A, Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces. These Agency standards are presented in OPPTS 810.2100.

Modifications for Copper Alloys: Modified versions of two acceptable Agency methods, combined with a novel method, were merged to generate a test system to represent residual self-sanitizing. The method, *Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces*, was modified to extend the contact time from 5 minutes to 120 minutes. Subsequent testing was modified to follow the *EPA Protocol for Residual Self-sanitizing Activity of Dried Chemical Residues on Hard Non-porous Surfaces*; these modifications included (1) changing the exposure time from 5 minutes to 120 minutes, and (2) replacing the coated antimicrobial surfaces with copper alloy surfaces. A third method was developed to show that copper surfaces could be effective after numerous, sequential re-inoculations. Briefly, the initial 5 µl inoculations were sequentially applied at 0, 3, 6, 12, 18, and 21 hours, resulting in 40 µl of inoculum applied over 24 hours. Next, multiple quantitative recoveries were performed at 2, 6, 12, 18, and 24 hours to access reductions from multiple inoculations. To support a claim for sanitizing and residual self-sanitizing efficacy of a copper alloy surface, a minimum of a 99.9% reduction in numbers of the test organism(s) on the test surface compared to the number of test organism(s) on the control surface must be achieve at all recovery times over two hours inoculation and exposure period. For 24 hours continuous reduction claims, a minimum of a 90% reduction (N. Whyte, Protocol review October 30, 2006).

Supplemental Recommendations: Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10^6 /ml) of conidia. These agency standards can be found in DIS/TSS-2.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 469996-10 "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces" for Alloy C51000 by Jill Ruhme. Study conducted at ATS Labs. Study completed November 7, 2006. Project Number A03147.

This test was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 3578486, 3578393, and 357823002) of alloy C51000 were tested, according to ATS Labs protocol number CSC02032905.CUST.3C, against

each of the target microorganisms for 2, 6, 12, 18, and 24 hours contact times at ambient temperature. The product was received ready-to-use. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five sterile carriers were tested per material, per organism, per time point for a total of 150 test carriers and 30 control carriers. Exposure began at time zero when 5 µl of the 24-54 hour old cultures was spread over each of the carriers, which were dried at ambient conditions throughout the exposure period. Carrier sets not removed for quantitative recovery were reinoculated as described above at 3, 6, 9, 12, 15, 18, and 21 hours. At 2, 6, 12, 18, and 24 hours, sets of test and control carriers were removed for quantitative recovery and transferred to 20 mL of Letheen Broth each to neutralize. Each neutralizer/carrier tube was sonicated for 5 minutes to remove survivors and serially diluted within one hour. Dilutions were plated in duplicate on Tryptic Soy Agar with 5% Sheep Blood (BAP). *S. aureus* plates were incubated at 35-37°C for 48±4 hours prior to observation and *E. aerogenes* plates were incubated at 25-30°C for 48±4 hours. Subcultures were stored at 2-8°C for two days prior to examination. Following incubation and storage, plates were visually enumerated. Subcultures showing growth were subcultured, stained and/or biochemically assayed (unspecified assay type) to confirm presence or absence of the test organism. Controls included those for purity, sterility, viability, neutralization confirmation, and inoculum and carrier quantitation.

Note: Protocol amendment reported in the study was reviewed and found to be acceptable.

Note: The study indicates the following claim(s) are supported by this data:
"This surface continuously reduces bacterial* contamination."
"This surface provides continuous/ongoing/persistent antimicrobial action even with repeated exposures."
"This surface continuously kills over 90% of bacteria* after repeated exposures during a day."
"This surface prevents the buildup of disease-causing bacteria*."
"This surface delivers continuous, long-lasting antibacterial* activity."
*[Including *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)]

2. MRID 469996-12 "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer" for Alloy C51000 by Jill Ruhme. Study conducted by ATS Labs. Study completed November 9, 2006. Project Number A03169.

This test was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 3578486, 3578393, and 357823002) of alloy C51000 were tested, according to ATS Labs protocol number CSC02032905.CUST.1C, against each of the target microorganisms for 120 minutes contact time at room temperature. The product was received ready-to-use. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five carriers were tested per material per organism. Each carrier was inoculated with a 0.02 mL aliquot of each 48±4 hour old culture and spread to within 1/8 inch of the carrier edges. Carriers were dried at room temperature for 20-40 minutes. Immediately following the drying period, the 120 minute

exposure period began. Following exposure, carriers were transferred to 20 mL of neutralizer (Letheen Broth) and sonicated for 5 minutes to suspend cells from carriers. Serial dilutions (10^{-1}-10^{-4}) of the neutralized solutions were prepared and plated in duplicate on BAP plates (Tryptic Soy Agar with 5% sheep blood) using standard spread plate technique. *S. aureus* plates were incubated at 35-37°C for 48±4 hours prior to observation. *E. aerogenes* plates were incubated at 25-30°C for 48±4 hours prior to observation. Following incubation, plates were visually enumerated. Cultures containing 30-300 colonies were used for calculations when possible. Controls included those for purity, sterility, viability, neutralization confirmation, inoculum count and carrier quantitation. The reported geometric mean colony forming units per carrier, for each test microorganism, are as follows:

Enterobacter aerogenes	**2.29×10^7**
Staphylococcus aureus	**1.20×10^6**

Note: Protocol amendment / deviation reported in the study were reviewed and found to be acceptable.

Note: The study indicates the following claim(s) are supported by this data:
"This surface kills greater than 99.9% of bacteria* within two hours"
*[Including *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)]

3. MRID 469996-13 "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces" for Alloy C51000 by Jill Ruhme. Study conducted by ATS Labs. Study completed November 9, 2006. Project Number A03170.

This test was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 3578486, 3578393, and 357823002) of alloy C51000 were tested, according to ATS Labs protocol number CSC02032905.CUST.2C, against each of the target microorganisms for 120 minutes contact time at ambient temperature. The product was received ready-to-use. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Four carriers were tested per material per organism per time point. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 35-37°C for 30 minutes at a 38-42% relative humidity. Immediately following drying, the 120 minute exposure period began at ambient conditions. After this exposure period, carriers were transferred to 30 mL neutralizer (Letheen Broth) jars and sonicated for 20±2 seconds in a sonicating waterbath and mixed on an orbital shaker for 3-4 minutes at 250 rpm. Neutralized samples were serially diluted in sterile deionized water and plated in duplicate within one hour of neutralization. *S. aureus* plates were incubated at 35-37°C and *E. aerogenes* plates were incubated at 25-30°C for 48±4 hours prior to evaluation. Following incubation, plates were visually enumerated. Cultures containing 30-300 colonies were used for calculations when possible. After this initial inoculation, a series of 12 wear cycles with dry and moist cloths with reinoculation and drying between each were conducted. Each wear cycle consisted of one pass to the left and a return pass to the right on a Gardner scrubber with an abrasion boat fitted with a foam liner and dry or wet cotton cloth. 15 minutes after each wear cycle, carriers were reinoculated and dried for at least 30 minutes. Following the last wear cycle, a final inoculation was performed with a 120 minute contact time and recovered as in the initial inoculation.

Controls included those for purity, sterility, viability, neutralization confirmation, and inoculum population.

Note: Protocol amendments reported in the study were reviewed and found to be acceptable.

Note: The study indicates the following claim(s) are supported by this data:
"This surface kills greater than 99.9% of bacteria* for 24 hours"
*[Including *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)]

4. MRID 469996-14 "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer" for Alloy C51000 by Jill Ruhme. Study conducted by ATS Labs. Study completed November 9, 2006. Project Number A03171.

This test was conducted against Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442). Two lots (Lot Nos. 3578486 and 3578393) of alloy C51000 were tested, according to ATS Labs protocol number CSC02032905.CUST.1D, against each of the target microorganisms for 120 minutes contact time at ambient temperature. The product was received ready-to-use. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five carriers were tested per material per organism. Each carrier was inoculated with a 0.02 mL aliquot of each 48±4 hour old culture and spread to within 1/8 inch of the carrier edges. Carriers were dried at room temperature for 20-40 minutes. Immediately following the drying period, the 120 minute exposure period began. Following exposure, carriers were transferred to 20 mL of neutralizer (Letheen Broth) and sonicated for 5 minutes to suspend cells from carriers. Serial dilutions (10^{-1}-10^{-4}) of the neutralized solutions were prepared and plated in duplicate on BAP plates (Tryptic Soy Agar with 5% sheep blood) using standard spread plate technique. Plates were incubated at 35-37°C for 48±4 hours prior to observation. Subculture plates were stored at 2-8°C for two days prior to observation. Following incubation and storage, plates were visually enumerated. Cultures containing 30-300 colonies were used for calculations when possible. Controls included those for purity, sterility, viability, neutralization confirmation, inoculum count and carrier quantitation. The reported geometric mean colony forming units per carrier, for each test microorganism, are as follows:

Methicillin Resistant *Staphylococcus aureus*	**1.95×10^7**
***Escherichia coli* O157:H7**	**9.12×10^4**
Pseudomonas aeruginosa	**7.94×10^6**

Note: Protocol amendments reported in the study were reviewed and found to be acceptable.

Note: The study indicates the following claim(s) are supported by this data:
"This surface kills greater than 99.9% of bacteria* within two hours"
*[Including Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442)]

5. MRID 469996-15 "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces" for Alloy C51000 by Jill Ruhme. Study conducted by ATS Labs. Study completed November 9, 2006. Project Number A03172.

This test was conducted against Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442). Two lots (Lot Nos. 3578486 and 3578393) of alloy C51000 were tested, according to ATS Labs protocol number CSC02032905.CUST.2D, against each of the target microorganisms for 120 minutes contact time at ambient temperature. The product was received ready-to-use. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Four carriers were tested per material per organism per time point. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 35-37°C for 30 minutes at a 38-42% relative humidity. Immediately following drying, the 120 minute exposure period began at ambient conditions. After this exposure period, carriers were transferred to 30 mL neutralizer (Letheen Broth) jars and sonicated for 20±2 seconds in a sonicating waterbath and mixed on an orbital shaker for 3-4 minutes at 250 rpm. Neutralized samples were serially diluted in sterile deionized water and plated in duplicate within one hour of neutralization. Plates were incubated at 35-37°C for 48±4 hours prior to evaluation. Following incubation, plates were visually enumerated. Cultures containing 30-300 colonies were used for calculations when possible. After this initial inoculation, a series of 12 wear cycles with dry and moist cloths with reinoculation and drying between each were conducted. Each wear cycle consisted of one pass to the left and a return pass to the right on a Gardner scrubber with an abrasion boat fitted with a foam liner and dry or wet cotton cloth. 15 minutes after each wear cycle, carriers were reinoculated and dried for at least 30 minutes. Following the last wear cycle, a final inoculation was performed with a 120 minute contact time and recovered as in the initial inoculation. Controls included those for purity, sterility, viability, neutralization confirmation, and inoculum population.

Note: Protocol amendments / deviation reported in the study were reviewed and found to be acceptable.

Note: The applicant provided the data for one failed trial. In that trial, the numbers controls were below the required number (at least 10^4 CFU/carrier) for the final *Escherichia coli* O157:H7. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. See Attachments I of the laboratory report.

Note: The study indicates the following claim(s) are supported by this data:
"This surface kills greater than 99.9% of bacteria* for 24 hours"
*[Including Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442)]

6. MRID 469996-16 "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces" for Alloy C51000 by Jill Ruhme. Study conducted at ATS Labs. Study completed November 6, 2006. Project Number A03850.

This test was conducted against Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442). Two lots (Lot Nos. 3578393 and 357823002) of alloy C51000 were tested, according to ATS Labs protocol number CSC02040406.CUST.3C, against each of the target microorganisms

for 2, 6, 12, 18, and 24 hours contact times at ambient temperature. The product was received ready-to-use. Fetal bovine serum was added to both cultures to create a 5% organic soil load supplemented with Triton X-100 (0.01%). Carriers consisted of 1" x 1" squares of the copper alloy test surface and 1" x 1" squares of stainless steel as a control surface. In preparation for the test, carriers were cleaned, rinsed with deionized water, and allowed to air dry. Carriers were flame sterilized prior to testing. Five sterile carriers were tested per material, per organism, per time point for a total of 150 test carriers and 30 control carriers. Exposure began at time zero when 5 µl of the 24-54 hour old cultures was spread over each of the carriers, which were dried at ambient conditions throughout the exposure period. Carrier sets not removed for quantitative recovery were reinoculated as described above at 3, 6, 9, 12, 15, 18, and 21 hours. At 2, 6, 12, 18, and 24 hours, sets of test and control carriers were removed for quantitative recovery and transferred to 20 mL of Letheen Broth each to neutralize. Each neutralizer/carrier tube was sonicated for 5 minutes to remove survivors and serially diluted within one hour. Dilutions were plated in duplicate on Tryptic Soy Agar with 5% Sheep Blood (BAP). Plates were incubated at 35-37°C for 48±4 hours prior to observation. Following incubation, plates were visually enumerated. Subcultures showing growth were subcultured, stained and/or biochemically assayed (unspecified assay type) to confirm presence or absence of the test organism. Controls included those for purity, sterility, viability, neutralization confirmation, and inoculum and carrier quantitation.

Note: The study indicates the following claim(s) are supported by this data:

"This surface continuously reduces bacterial* contamination."

"This surface provides continuous/ongoing/persistent antimicrobial action even with repeated exposures."

"This surface continuously kills over 90% of bacteria* after repeated exposures during a day."

"This surface prevents the buildup of disease-causing bacteria*."

"This surface delivers continuous, long-lasting antibacterial* activity."

*[Including Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442)]

7. The following additional studies were also submitted but not reviewed, as they were conducted as part of the protocol development process and are not intended to support product registration (per June 7, 2007 letter from the applicant's representative).

MRID	Method	Organisms
469996-04	Bacteria Reduction	*S. aureus, E. aerogenes*
469996-05	Residual Bacteria Reduction	*S. aureus, E. aerogenes*
469996-06	Continuous Reduction	*S. aureus, E. aerogenes*
469996-07	Bacteria Reduction	MRSA, *E. coli* O157:H7, *P. aeruginosa*
469996-08	Residual Bacteria Reduction	MRSA, *E. coli* O157:H7, *P. aeruginosa*
469996-09	Continuous Reduction	MRSA, *E. coli* O157:H7, *P. aeruginosa*
469996-11	Continuous Reduction	MRSA, *E. coli* O157:H7, *P. aeruginosa*
469996-17	Bacteria Reduction	*S. aureus, E. aerogenes*

V. RESULTS

MRID	Organism	Results (Mean Survivors CFU /Carrier)				Percent Reduction
		Steel Carrier Control	Lot 3578486	Lot 3578393	Lot 357823002	
469996-12	*S. aureus*	1.20×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
	E. aerogenes	2.29×10^7	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
469996-14	MRSA	1.95×10^7	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9
	E. coli O157:H7	9.12×10^4	$<1.00 \times 10^2$	$<1.00 \times 10^2$	-	>99.9
	P. aeruginosa	7.94×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	-	>99.9

MRID	Organism	Exposure Time (Hours)	Results (Mean Survivors CFU/Carrier)				Percent Reduction
			Steel Carrier Control	Lot 3578486	Lot 3578393	Lot 357823002	
469996-10	*S. aureus*	2	5.13×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		6	4.17×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		12	8.71×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		18	1.20×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		24	7.08×10^5	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
	E. aerogenes	2	1.12×10^7	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		6	9.12×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		12	6.17×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		18	2.40×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		24	5.75×10^6	$<2.00 \times 10^2$	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
469996-16	MRSA	2	3.47×10^5	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		6	9.33×10^5	-	$<3.31 \times 10^2$	$<9.12 \times 10^2$	>99.9
		12	1.48×10^6	-	3.02×10^2	$<2.88 \times 10^2$	>99.9
		18	2.24×10^7	-	2.24×10^3	5.50×10^2	>99.9
		24	3.09×10^7	-	2.75×10^2	2.51×10^2	>99.9
	E. coli O157:H7	2	8.91×10^4	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.8
		6	7.59×10^4	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.7
		12	5.50×10^4	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.6
		18	2.14×10^5		$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		24	2.14×10^5	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
	P. aeruginosa	2	2.09×10^5	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		6	1.62×10^5	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		12	1.23×10^5	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.8
		18	3.47×10^5	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9
		24	2.75×10^5	-	$<2.00 \times 10^2$	$<2.00 \times 10^2$	>99.9

MRID	Organism		Results (Mean Survivors CFU /Carrier)				Percent Reduction
			Steel Carrier Control	Lot 3578486	Lot 3578393	Lot 357823002	
469996-13	*S. aureus*	Initial	9.55×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	$<3.02 \times 10^1$	>99.9
		Final	1.32×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	$<3.02 \times 10^1$	>99.9
	E. aerogenes	Initial	1.26×10^6	$<3.02 \times 10^1$	$<3.02 \times 10^1$	$<3.02 \times 10^1$	>99.9
		Final	5.37×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	$<3.02 \times 10^1$	>99.9
469996-15	MRSA	Initial	2.29×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	-	>99.9
		Final	2.14×10^6	2.40×10^4	2.57×10^3		99.4
	MRSA (RPT)	Initial	5.13×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	-	>99.9
		Final	1.32×10^6	$<4.90 \times 10^1$	2.95×10^2		>99.9
	E. coli O157:H7	Initial	1.10×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	-	>99.9
		Final	7.08×10^4	$<3.02 \times 10^1$	$<3.02 \times 10^1$		>99.9
	P. aeruginosa	Initial	2.57×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$	-	>99.9
		Final	2.82×10^5	$<3.02 \times 10^1$	$<3.02 \times 10^1$		>99.9

VI. CONCLUSIONS

1. The submitted efficacy data (MRID Nos. 469996-12 and 469996-14) **support** the use of the surfaces of the product, Antimicrobial Copper Alloys-Group I, as surfaces with bacteria reduction activity against *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442) on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 120 minutes at ambient temperature.

2. The submitted efficacy data (MRID Nos. 469996-13 and 469996-15) **support** the use of the surfaces of the product, Antimicrobial Copper Alloys-Group I, as surfaces with residual bacterial reduction activity against *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442) on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 120 minutes at ambient temperature.

3. The submitted efficacy data (MRID Nos. 469996-10 and 469996-16) **support** the use of the surfaces of the product, Antimicrobial Copper Alloys-Group I, as surfaces with continuous reduction activity over 24 hours period against *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442) on hard, non-porous surfaces in the presence of a 5% organic soil load at ambient temperature.

VII. RECOMMENDATIONS

1. The proposed label claims that the surfaces of Antimicrobial Copper Alloys-Group I effectively reduce 99.9% of *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442) when used for a contact time of 120 minutes, **are supported** by the applicant's data.

2. The proposed label claims that the surfaces of Antimicrobial Copper Alloys-Group I effectively reduce 99.9% of *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442) when used for a contact time of 120 minutes, **are supported** by the applicant's data.

3. The proposed label claims that the surfaces of Antimicrobial Copper Alloys-Group I, continuously reduce 99% of bacteria [*Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), Methicillin Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* O157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442)] over 24 hours period, **are supported** by the applicant's data.

4. Initial cleaning directions and maintenance directions

In review of the submitted efficacy studies, it is apparent that cleaning is required to elicit and maintain 3-log reduction in efficacy. An initial cleaning or "degreasing step" should be included on the label to address removal of residual manufacturing oil and debris. This initial cleaning step will be reserved for newly incorporated surfaces and sites. For claims of continuous, long-lasting activity and residual activity, a maintenance cleaning step should be included on the proposed label. The language for this maintenance cleaning step should indicate that high touch surfaces with significant bioload should be subjected to daily cleaning to elicit continued efficacy, as demonstrated in the test systems. As an extension of label cleaning verbiage, agents compatible with the copper surfaces should be included.

4. Surface Limitations

"Practical" surfaces can remain on the label, when acceptable cleaning directions are provided

Surfaces to be removed from the Label

- Remove all outdoor surfaces from the label (playground equipment) as the efficacy test performed do not adequately represent conditions the surfaces would be exposed to in an outdoor environment.

- Remove all textiles (uniforms, curtains, sheets, pillow cases), as these are porous surfaces for which efficacy has not been demonstrated.

- Remove shopping cart handles and child seats from the proposed label. These surfaces are extremely high-touch surfaces, unlikely to be cleaned every 24 hours. Furthermore these surfaces are likely to be left outside for extended periods.

- Surfaces that are **high-touch surfaces with significant bioload** and aren't practical to clean on a consistent basis (therefore efficacy may not be demonstrated if cleaning is not performed on a daily/routine basis. The rationale for removing these surfaces is based on efficacy data. You may re-iterate that daily cleaning is mandatory for high-touch surfaces that may undergo frequent re-colonization. These surfaces are:

  Healthcare Facilities
  Bedrails, footboards
  Bedrails, assistance rails
  Paper towel holders
  Alcohol sanitizer dispenser handles
  Showerheads
  Visitor chairs, armrest, metal frames
  Closures
  Vertical locking arms
  Vertical cover guards
  Protection bars
  Thermostat covers
  Telephone handsets and surfaces (housings) keyboards
  Ceiling tiles (request additional information, regarding types, often these are porous)
  Walkers, wheelchair handles, and tubular components
  Computer keyboards: keys, housings, computer mouse
  Medical records: chart holders, clipboards, filing systems
  Storage shelving: wire shelving etc. for medical supplies

  Community Facilities
  Cash registers: housing, keypads
  ATM machines: keys, housing (must be indoor)
  Gym/Health club lockers, locker handles locker shelving, trainers' tables
  Ice and water dispensers (outer surfaces without water contact)
  Windows (crank), Locking mechanism, pull handles
  Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
  Jalousie Windows (crank)
  Casement (cranks, levers, hinges)
  Single and double-hung windows (locks and pulls)

5. The applicant must make the following changes to the proposed label, as appropriate:

On page 5 of the proposed label (mid-way through the list of use surfaces), add non-food contact only in parenthesis next to "countertops and tabletops"

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